

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### comparison of low level laser acustimulation and no intervention on gag reflex management on patients undergoing maxillary impression

#### Protocol summary

##### Study aim

effect of low level laser acustimulation on gag reflex

##### Design

this parallel group single blind phase 2-3 randomised trial was performed on 30 - allocated by site to case and control groups - .

##### Settings and conduct

30 patients were enrolled from Mashhad Dental School . before impression gag reflex severity was measured by GPI ( GAG PREVENTION INDEX) including : 1- tolerance of alginate tray until complete setting 2- tolerance of alginate tray just in initial placement 3- tolerance of empty tray 4- intolerance of tray in oral cavity to asses subjective gag reflex severity VAS(Visual Analog Scale) was used . in a ruler numbering 0 to 10 . zero representing no gag reflex and 10 representing the worst gag reflex even experienced. number of vomiting cycles also was registered . in intervention group low level laser (Ga-Al-As) 810nm was irradiated for 1 minute to cv 24 and P6 acupuncture points . after irradiation impression was achieved in 3 mins and severity of gag reflex was registered .in control group all steps were similar except that laser was switched off.this was performed to assess placebo effect.

##### Participants/Inclusion and exclusion criteria

patients admitted to Mashhad Dental school needing alginate impression for prosthodontic or orthodontic treatment ,20 to 60 years old suffering from severe gag reflex

##### Intervention groups

in intervention group GaAlAs 810 nm,200Mw low level laser was applied on P6,Cv24 acupuncture points for 1 minute. the skin was disinfected by alcohol and the laser probe was applied on 1 cm distance from skin . in control group all situation was similar except that laser was switched off.

##### Main outcome variables

gag reflex severity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20080906001216N4**

Registration date: **2020-11-29, 1399/09/09**

Registration timing: **retrospective**

Last update: **2020-11-29, 1399/09/09**

Update count: **0**

##### Registration date

2020-11-29, 1399/09/09

##### Registrant information

##### Name

Pegah Mosannen Mozaffari

##### Name of organization / entity

research center of Mashhad dental faculty, Mashhad University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 513882950115

##### Email address

mosannenp@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-09-23, 1396/07/01

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

2017-09-23, 1396/07/01

##### Actual recruitment end date

2018-05-22, 1397/03/01

##### Trial completion date

2018-06-22, 1397/04/01

**Scientific title**

comparison of low level laser acustimulation and no intervention on gag reflex management on patients undergoing maxillary impression

**Public title**

effect of low level laser acustimulation on gag reflex management

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

patient admitted to Mashhad Dental School suffering severe Gag reflex need Alginate impression for denture fabrication or orthodontic treatment

**Exclusion criteria:**

disagreement to participate in trial

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **30**

Actual sample size reached: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

allocation to two groups by <http://www.randomizer.org> (two groups A and B)

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

patient was blind about sham laser

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Mashhad University of Medical Sciences-Research Ethics Committee

**Street address**

Vakil Abad BLV

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

911735984

**Approval date**

2018-09-12, 1397/06/21

**Ethics committee reference number**

IR.MUMS.DENTISTRY.REC.1397.047

**Health conditions studied****1****Description of health condition studied**

gag reflex

**ICD-10 code**

R11

**ICD-10 code description**

Nausea and vomiting

**Primary outcomes****1****Description**

gag reflex management

**Timepoint**

just after intervantion

**Method of measurement**

GPI = gag prevention index

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: in this group low level laser acustimulation on accumuncture points for controlling gag reflex (cv24 ,pc6) was performed before obtaining maxillary impression

**Category**

Prevention

**2****Description**

Control group: in this group sham laser (placebo)was placed on accumuncture points for controlling gag reflex (cv24 ,pc6) before obtaining maxillary impression.

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Mashhad Dental School

**Full name of responsible person**

Pegah Mosannen Mozafari

**Street address**

Vakil Abad Blv

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

+98 51 3882 9501

**Fax**

+98 51 8882 9500

**Email**

mosannenp@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Vakil Abad Blv

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91388-13944

**Phone**

+98 51 3882 9501

**Fax**

+98 51 3882 9500

**Email**

tafaghodiM@mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Pegah Mosannen Mozafari

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Vakil Abad BLV

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

+98 51 3882 9501

**Fax**

+98 51 3882 9500

**Email**

mosannenp@mums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Pegah Mosannen Mozafari

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Vakil Abad BLV, Front of Mellat Park, Mashhad

Dental School

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

911735984

**Phone**

+98 51 3882 9501

**Fax**

+98 51 3882 9500

**Email**

mosannenp@mums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

pegah Mosannen Mozafari

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Vakil Ababd BLV

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

911735984

**Phone**

+98 51 3882 9501

**Fax**

+98 51 3882 9500

**Email**

mosannenp@mums.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

data including demographic data signs and symptoms and intervention results will be released

**When the data will become available and for how long**

2 months after article publication

**To whom data/document is available**

academic staff

**Under which criteria data/document could be used**

the data can be used in further studies with citation to main article

**From where data/document is obtainable**

pegah mosannen mozafari

**What processes are involved for a request to access data/document**

email communication , the data will be sent in 4 weeks

**Comments**